Commercial PA Criteria

Effective: May 3, 2017

Prior Authorization: Kisqali (ribociclib)

Products Affected: Kisqali (ribociclib) oral tablets

Medication Description:
Kisqali is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. Additionally, Kisqali is indicated for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy; or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

Kisqali belongs to a class of cyclin-dependent kinase (CDK) inhibitors and blocks CKD 4/6. Kisqali reduces cellular proliferation of estrogen receptor-positive breast cancer cells by blocking the G1 phase of the cell cycle, which when combined with an aromatase inhibitor, increases the inhibition of retinoblastoma protein phosphorylation, downstream signaling, and tumor growth.

Covered Uses:

1. **Early Breast Cancer:** Kisqali, in combination with an aromatase inhibitor, and Kisqali Femara Co-Pack are indicated for the adjuvant treatment of stage II and III early breast cancer at high risk of recurrence.
2. **Advanced or Metastatic Breast Cancer:** In combination with an aromatase inhibitor (AI) as initial endocrine-based therapy;
3. **Advanced or Metastatic Breast Cancer:** Kisqali (not Co-Pack) in combination with fulvestrant as initial endocrine based therapy or following disease progression on endocrine therapy;

Exclusion Criteria:
Kisqali has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. As monotherapy
2. Patient is pregnant.

Required Medical Information:

1. Estrogen receptor (ER) status
2. Human epidermal growth factor receptor status
3. Menopause status
4. Previous therapies

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist

Coverage Duration: 3 years

Other Criteria:

1. **Breast Cancer in Women-** Approve if the patient meets ALL of the following (A, B, C, D, E, **AND** F):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient meets ONE of the following (i **OR** ii):
      i. As per the prescriber, medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; **OR**
      ii. Patient has recurrent or metastatic disease; **AND**
   C. Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; **AND**
   D. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   E. Patient meets ONE of the following (i **OR** ii):
      i. Patient is postmenopausal; **OR**
      ii. Patient is pre/perimenopausal and meets ONE of the following (a **or** b):
         a. Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; **OR**
            Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
         b. Patient has had surgical bilateral oophorectomy or ovarian irradiation; **AND**
   F. Patient meets ONE of the following (i **OR** ii):
      i. Kisqali will be used in combination with anastrozole, exemestane, or letrozole; **OR**
      ii. Kisqali will be used in combination with fulvestrant.

2. **Breast Cancer in Men** - Approve if the patient meets ALL of the following (A, B, C, D, E, **AND** F):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient meets ONE of the following (i **OR** ii):
      i. As per the prescriber, the medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; **OR**
      ii. Patient has recurrent or metastatic disease; **AND**
   C. Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; **AND**
   D. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; **AND**
   E. Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; **AND**
      Note: Examples of GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
   F. Patient meets ONE of the following (i **OR** ii):
      i. Kisqali will be used in combination with anastrozole, exemestane, or letrozole; **OR**
      ii. Kisqali will be used in combination with fulvestrant.

References:

1. Kisqali® tablets [prescribing information]. East Hanover, NJ: Novartis; September 2024.
2. Clinical Pharmacology [database online]. Ribociclib drug information. Tampa, FL: Gold Standard, Inc.; 2017. URL: http://www.clinicalpharmacology.com. Accessed March 27, 2017.
3. The National Comprehensive Cancer Network. NCCN Guidelines for Breast Cancer. Updated March 10, 2017. URL: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 27, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/14/2017
2	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
3	Update	Adopted EH policy onto CCI template	ALL	08/22/2023
4	Update	Breast Cancer in Women: added criteria for approval in early breast cancer for adjuvant therapy based on FDA approval. Breast Cancer in Men: added criteria for approval in early breast cancer for adjuvant therapy based on FDA approval. In addition, for Kisqali, based on prescribing information, reformatted criterion requiring gonadotropin-releasing hormone (GnRH) analog such that it is used either with an aromatase inhibitor or fulvestrant.	Products Affected Medication description Covered Uses Other Criteria Coverage duration	12/16/2024